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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,164	06/19/2003	Sudeep M. Kumar	100390-06430	9722

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EXAMINER	
TURK, NEIL N	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/600,164	KUMAR ET AL.	
	Examiner	Art Unit	
	Neil Turk	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/29/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 29-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 29-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/16/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks made on January 29th, 2007. Claims 1-27 and 29-58 are pending. Claims 59-61 are withdrawn from consideration. Claim 28 has been cancelled.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-36, in the reply filed on January 29th, 2007 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and there would not be a serious burden on the Examiner to search all of the groups. In view of the amendments made to the claims, the Examiner has rejoined group II, claims 37-58, and thereby claims 1-27 and 29-58 are pending. The invention of group III, claims 59-61 is still deemed to be independent and distinct because of the previously recited reasons and would impose a serious burden on the Examiner to search the additional claims. Claims 1-58 only require a working electrode of particular composition and a light detector and/or a transparent portion of the cell in registration with the working electrode. Claims 59-61 require forming a composition of an electrochemiluminescence label and co-reactant along with other elements including a field extending element and further require applying electrical energy and measuring the emitted electrochemiluminescence all of which are not required by claims 1-58.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23, and 56-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1-99% weight percent iridium, does not reasonably provide enablement for 50-95% weight percent iridium as is currently being claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claims 22, 23, and 56-58 recite a working or counter electrode which is an iridium alloy with a second predetermined weight of another element from 5% to 50% (thereby the Ir would be 50% to 95%). Applicant's specification on page 24 recites that the weight percentage of Ir is preferably 1-99%, more preferably 5-50%, more preferably 5-30%, and most preferably 10-30%. As Applicant discloses a range of 1-99% for the Ir, Applicant has provided support for the 50-95% Ir as being currently claimed. However, from reading the specification it is unclear if this is the range Applicant intended to claim given that there is no 50-95% range specifically mentioned and further, all the more preferable ranges decrease in the percentage of Ir. Examiner notes that the prior art, such as that disclosed by Heusler (4,252,617), teaches a platinum-iridium alloy electrode in which the iridium is 10% by weight.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 and 37-58 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the structural relationship of the working electrode to the counter electrode and the counter electrode with the light detector. The claims recite a working electrode and counter electrode, and a light detector and/or transparent portion that is in optical registration with the working electrode. However, it is unclear how the working electrode is structurally related to the counter electrode and further it is unclear how the counter electrode is related to the light detector and/or transparent portion.

Claims 6-19, 41, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears that there are some formalities that need to be addressed with regard to the dependent claim limitations with respect to the newly amended independent claims. The above claims contain limitations to "said electrode" for which there is no antecedent basis given the amendments made to the independent claims respective to the above claims, and it is thereby unclear if the working electrode or counter electrode is being claimed. Further, the above claims

contain recitations to the cell further comprising a counter electrode. This can be seen in claims 9 and 10, for example. As independent claim 1 recites a counter electrode, it is unclear if Applicant intends to recite an additional counter electrode or if Applicant intended to cancel such claims as their limitations are placed in the independent claim.

Claims 37-58 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: claims 37-58 are drawn to method claims, but the claims do not recite method steps for accomplishing such an assay. The method claims merely recite the structural elements that are claimed in the preceding apparatus claims of 1-36. As such, in the claims which do not set forth method steps, prior art which reads on the apparatus claims will be taken to read on such method claims. Further, the recitation in the preamble of the independent method claims to that of, "...comprising the step of inducing electrochemiluminesence..." will be taken such that given the same disclosed structural elements, the apparatus will be taken to be capable of performing such a step of inducing electrochemiluminescence. If Applicant intends to recite a method Applicant must establish specific method steps within the independent claims. Examiner points to claim 43 which recites actual method steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 20, 21, 24, and 37-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama (5,993,740) in view of Bard (3,900,418) and in view of Tench (4,132,605).

Niyama discloses an electrochemiluminescence cell and method of its use. Niyama discloses that the cell includes working electrode 15, counter electrodes 16a, 16b, window 22 and light sensor 19 (photodetector, pmt, photodiode)(abstract, lines 44-49, col. 3; lines 48-67, col. 7; col. 8; figs. 2-4). Niyama discloses that the electrodes may be made of such materials as platinum, iridium, tungsten and alloys there of such that these materials prevent wear and corrosion from reaction and reagents flowing on the electrode surfaces (lines 23-29, col. 5); Niyama shows in figures 5A-F forms of models including a magnetic particle 40 (trapped in the chamber by way of a magnet over the working electrode, lines 62-67 col. 4), first reagent 44, TSH 47 as the analyte in the sample, second reagent 48, reaction product 54 and TPA as the attractant in the buffer solution. Niyama also discloses that TPA (tripropylamine) is the attractant contained in the buffer solution, which is reduced upon application of a voltage so as to excite the label material and has a pH of about 7.4, and additionally the second reagent 48 has fixed to $Ru(bpy)_3$ (ruthenium-tris-bipyridine) as the label material (lines 44-48, col. 7; lines 65-67, col. 11; lines 1-13, col. 12, fig 5A-F).

Niyama does not disclose a working electrode or counter electrode that comprises a platinum alloy with a second element having a 5 to 50 (and also 10 to 30%) weight percent. Niyama also does not disclose a working electrode or counter electrode

that comprises rhodium or a rhodium alloy with a second element having a 5 to 50 (and also 10 to 30%) weight percent.

Bard discloses electrochemical luminescent solutions and devices for incorporating such solutions. Bard discloses that the electrode is generally of a noble metal, with typical examples being platinum, gold, rhodium, and palladium. Bard discloses that the electrodes are universal in that any of the above electrode materials can be used with any EGCL (also referred to as ECL) solution (lines 24-28, col. 3).

Tench discloses a method for evaluating the quality of electroplating baths in which three electrodes are utilized: a working electrode 13, a counter electrode 15, and a reference electrode 17 within the cell 19. Tench discloses that in one embodiment the counter electrode 15 is platinum-10% rhodium (lines 43-59, col. 3, fig. 2). Examiner asserts that a counter electrode of platinum-10%rhodium constitutes both a platinum alloy and a rhodium alloy.

It would have been obvious to modify Niyama to include an electrode of rhodium such as taught by Bard and to include a counter electrode of a platinum alloy with 10% rhodium as a second element and to include a counter electrode of a rhodium alloy with 90% platinum as a second element such as taught by Tench in order to provide Niyama with an electrode of another noble metal such that Niyama discusses noble metals and their alloys for working and counting electrodes so as to provide an electrode resistant to corrosion and war and to provide a known alloy composition suitable for a counter electrode.

Claims 10-19 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Bard and in view of Tench as applied to claims 1-9, 20, 21, 24, and 37-55 and in further view of Wohlstadter (6,207,369).

Niyama/Bard/Tench does not disclose that the support for the counter electrode is transparent and that the counter electrode includes a field extending element.

Wohlstadter discloses an electrochemiluminescent cell and method of its use. Wohlstadter also discloses that commercial ECL assays are performed using a flow cell with a working and counter electrode. Wohlstadter also discloses the use of a waveform generator/potentiostat as a source of electrical energy (lines 4-12, col. 12). Wohlstadter discloses that the cell may have electrodes with field extending structures as shown in figures 6b and 19a-e, and such combinations provide for a constant electric field and supports for the electrodes may be of any material, including transparent materials (lines 1-10, col. 44; col. 42-44).

It would have been obvious to modify the Niyama/Bard/Tench device to include a transparent support and a field extending element such as taught by Wohlstadter in order to provide a constant electric field and a support of a suitable material to observe/detect reactions by optical means.

Claims 1-21 and 24-55 are rejected under 35 U.S.C. 103(a) as being obvious over Liljestrand (6,200,531) in view of Niyama and in view of Bard and in view of Tench and in view of Kovacs (5,965,452).

Liljestrand discloses an apparatus for carrying out electrochemiluminescence test measurements. Liljestrand discloses that the prior art includes a flow cell (US Patent No. 5,466,416) that comprises a counter electrode 26, ECL test chamber 28, working electrode 30, transparent 32, and the flow cell 18 includes a main housing 48 formed of a transparent, chemically inert material. Liljestrand also discloses that working electrode 30, counter electrode 26, and counter electrode 34 may consist of electrically-conductive materials such as platinum (lines 7-10, col. 2, fig. 1&2). Liljestrand further discloses that counter electrode 26 is affixed to a side of transparent block 32. Liljestrand discloses that the counter electrode 136 may comprise a mesh or a screen and counter electrode 136 is shaped to fit a counter electrode groove in component 134 and may be "L" shaped or "T" shaped advantageously such that one "arm" of the configuration may be positioned to extend beyond component 142 to provide the provision of electrical energy (lines 58-67, col. 12; lines 1-5, col. 13). Liljestrand also discloses reference electrode 128 is an ECL reference electrode for detecting the voltage level of an assay sample (lines 23-36, col. 12). Liljestrand further discloses that the invention may also include a photodetector, e.g. a photodiode, in optical registration with the electrically-shielded window, the transparent portion of the cell wall and the working electrode (lines 33-36, col. 5). Liljestrand also discloses that a removable magnet is provided for applying a magnetic field to the working electrode (lines 37-42, col. 5). Liljestrand further discloses that registration of working electrode 140, opening 137, opening 133 (of the counter electrode 136), transparent base 127, aperture 125, conductive window 124, optical filter 123 and light detector 122 is necessary in order to

provide optimal transmittance of light from the working electrode to the light detector, and opening 133 functions as an optical element the defines the electrochemiluminescence that may propagate to the light detector. Liljestrand also discloses that the counter electrode may be designed to block undesired light generated in certain regions (lines 41-67, col. 14, fig. 3a). Liljestrand also discloses that electrical energy is supplied to flow cell 120 through working electrode 140 and counter electrode 136 by application of main controller 214 (waveform generator/potentiostat included in main controller 214) to cause the input fluid to electrochemiluminescence (lines 39-42, col. 17; lines 15-23, col. 18).

Liljestrand does not disclose the specific compositions of the platinum and rhodium alloys for the counter or working electrode. Liljestrand also does not disclose a counter electrode with a field extending element, where the counter electrode is not a mesh or screen and the field extending element is a ladder electrode, and also does not disclose that the field extending element reduces the electrochemiluminescence incident upon the transparent portion by less than 50%.

Niyama, Bard, and Tench have been discussed above.

Kovacs discloses a biological electrode array in which in an embodiment for incorporating optical fluorescence or transmittance detection circuitry into the electrode matrix 12 it is desirable to provide a slitted or punctuated electrode structure, such as that shown in figure 8(b). Examiner asserts that such an electrode as disclosed and shown in figure 8b by Kovacs constitutes a ladder electrode by Applicant's definition given in paragraph 0096 of the pre-grant publication (2004/0090168). Orifices 56 allow

the passage of light through the electrode 52 to the optical detector 50, thus eliminating the need for an external camera and reducing the analysis system cost (lines 30-65, col. 8, fig. 8b). Examiner further asserts that since figure 8b shows five troughs 56 for the passage of light to the detector, and there are six equally sized portions of the electrode along with the backbone side on the left which would block the passage of light, thereby such a ratio of the structures blocking passage of light to that of those allowing passage would constitute allowing less than 50% incident electrochemiluminescence.

It would have been obvious to modify Liljestrand to include an electrode of rhodium and to include a counter electrode of a platinum alloy with 10% rhodium as a second element and to include a counter electrode of a rhodium alloy with 90% platinum as a second element such as taught by Niyama, Bard, and Tench in order to provide Liljestrand with an electrode of a noble metal alloy for resistance to corrosion and wear and to thereby provide a known alloy compositions suitable for a counter electrode. It would have been obvious to modify Liljestrand to include a field extending element that is not a mesh or screen such as taught by Kovacs in order to provide a design to the counter electrode which provides selective transmittance of the generated electrochemiluminescence to the detector and selectively blocks light incident to the detector.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT